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PATENT COOPERATION TREATY

From the INTERNATIONAL BUREAU

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

To:

Assistant Commissioner for Patents
United States Patent and Trademark Office
Box PCT
Washington, D.C.20231
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 19 October 2000 (19.10.00)	
International application No. PCT/US00/03871	**Applicant's or agent's file reference** 23660-00623
International filing date (day/month/year) 04 February 2000 (04.02.00)	**Priority date** (day/month/year) 05 February 1999 (05.02.99)
Applicant TROUT, Hugh, III et al	

1. The designated Office is hereby notified of its election made:

[X] in the demand filed with the International Preliminary Examining Authority on:

05 September 2000 (05.09.00)

[ ] in a notice effecting later election filed with the International Bureau on:

2. The election [X] was

[ ] was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer Antonia Muller
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

09/936202

3

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 23660-00623	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US00/03871	International filing date *(day/month/year)* 04 FEBRUARY 2000	Priority date *(day/month/year)* 05 FEBRUARY 1999
International Patent Classification (IPC) or national classification and IPC IPC(7): A61B 17/04 and US Cl.: 606/148		
Applicant EVA CORPORATION		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 3 sheets.

   ☐ This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority. (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 0 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☐ Non-establishment of report with regard to novelty, inventive step or industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
05 SEPTEMBER 2000	20 APRIL 2001
Name and mailing address of the IPEA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer LIEN NGO Telephone No. (703) 305-0294

Form PCT/IPEA/409 (cover sheet) (July 1998) ★

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/03871

I. Basis of the report

1. With regard to the **elements** of the international application: *

[X] the international application as originally filed

[X] the description:
pages 1-11 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the claims:
pages 12-14 , as originally filed
pages NONE , as amended (together with any statement) under Article 19
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the drawings:
pages 1-8 , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

[X] the sequence listing part of the description:
pages NONE , as originally filed
pages NONE , filed with the demand
pages NONE , filed with the letter of _____

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.
These elements were available or furnished to this Authority in the following language _____ which is:

[ ] the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

[ ] the language of publication of the international application (under Rule 48.3(b)).

[ ] the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

[ ] contained in the international application in printed form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] The statement that the information recorded in computer readable form is identical to the writen sequence listing has been furnished.

4. [X] The amendments have resulted in the cancellation of:

[X] the description, pages NONE

[X] the claims, Nos. NONE

[X] the drawings, sheets/~~fig~~ NONE

5. [ ] This report has been drawn as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

** Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).*

***Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.*

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.
PCT/US00/03871

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. statement

Novelty (N)	Claims	NONE	YES
	Claims	1-22	NO
Inventive Step (IS)	Claims	NONE	YES
	Claims	1-22	NO
Industrial Applicability (IA)	Claims	1-22	YES
	Claims	NONE	NO

2. citations and explanations (Rule 70.7)

Claims 1-19 lack novelty under PCT Article 33(2) as being anticipated by Wilson et al. (5,447,512). Wilson et al. disclose, in figs. 1,5, 8 and 10, a surgical guide line assembly comprising a a guide line component 20, a suture 25 secured to the distal end of said guide line component, a control assembly 26, a needle 46 connected to said suture and a broad line 28 assembly produce a flexible curved end portion of said guide line assembly.

Claims 1-19 lack novelty under PCT Article 33(2) as being anticipated by Camps et al. (5,314, 463) Camps et al. disclose, in figs. 1 and 18) a surgica; guide lines substantially as claimed.

Claims 20-22 lack novelty under PCT Article 33(2) as being anticipated by Ovil et al. (4,702,250). Ovil et al. disclose, in figs, 12 and 23, a surgical separator assembly comprising separate means 212, advancing means 208 and control means 248.

---------- NEW CITATIONS ----------

NONE

23660-623-25 JR

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

JUN 20 2000

To: PATRICK J. COYNE
COLLIER, SHANNON, RILL & SCOTT, PLLC
3050 K STREET, N.W., SUITE 400
WASHINTON DC 20007

PCT

NOTIFICATION OF TRANSMITTAL OF THE INTERNATIONAL SEARCH REPORT OR THE DECLARATION

(PCT Rule 44.1)

	Date of Mailing *(day/month/year)* 13 JUN 2000
Applicant's or agent's file reference 23660-00623	**FOR FURTHER ACTION** **See paragraphs 1 and 4 below**
International application No. PCT/US00/03871	International filing date *(day/month/year)* 04 FEBRUARY 2000
Applicant EVA CORPORATION	

1. [X] The applicant is hereby notified that the international search report has been established and is transmitted herewith.

Filing of amendments and statement under Article 19:
The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally 2 months from the date of transmittal of the international search report; however, for more details, see the notes on the accompanying sheet.

Where? Directly to the International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland
Facsimile No.: (41-22) 740.14.35

For more detailed instructions, see the notes on the accompanying sheet.

2. [ ] The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect is transmitted herewith.

3. [ ] **With regard to the protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

[ ] the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.

[ ] no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Further action(s):** The applicant is reminded of the following:

Shortly after **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in rules 90 *bis* 1 and 90 *bis* 3, respectively, before the completion of the technical preparations for international publication.

Within **19 months** from the priority date, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later).

Within **20 months** from the priority date, the applicant must perform the prescribed acts for entry into the national phase before all designated Offices which have not been elected in the demand or in a later election within 19 months from the priority date or could not be elected because they are not bound by Chapter II.

Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231	Authorized officer LIEN NGO
Facsimile No. (703) 305-3230	Telephone No. (703) 305-0294

Form PCT/ISA/220 (July 1998) ★ *(See notes on accompanying sheet)*

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 23660-00623	FOR FURTHER ACTION	see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.
International application No. PCT/US00/03871	International filing date *(day/month/year)* 04 FEBRUARY 2000	(Earliest) Priority Date *(day/month/year)* 05 FEBRUARY 1999
Applicant EVA CORPORATION		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 3 sheets.

[X] It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

[ ] the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing:

[ ] contained in the international application in written form.

[ ] filed together with the international application in computer readable form.

[ ] furnished subsequently to this Authority in written form.

[ ] furnished subsequently to this Authority in computer readable form.

[ ] the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

[ ] the statement that the information recorded in computer readable form is identical to the written sequence listing has b een furnished.

2. [ ] **Certain claims were found unsearchable** (See Box I).

3. [ ] **Unity of invention is lacking** (See Box II).

4. With regard to the **title**,

[X] the text is approved as submitted by the applicant.

[ ] the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

[ ] the text is approved as submitted by the applicant.

[X] the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No. 2

[X] as suggested by the applicant.

[ ] because the applicant failed to suggest a figure.

[ ] because this figure better characterizes the invention.

[ ] None of the figures.

Box III TEXT OF THE ABSTRACT (Continuation of item 5 of the first sheet)

The technical features mentioned in the abstract do not include a reference sign between parentheses (PCT Rule 8.1(d)).

ABSTRACT

The present invention is directed to a surgical guide line assembly (10) for use during a surgical procedure. The surgical guide assembly (10) permits the manipulation of a surgical component within a vessel during a surgical procedure, such as for example and intravascular procedure. The surgical guide line assembly (10) includes a guide line component (11) having a proximal end and a distal end, and at least one suture (12) secured to the dital end of the guide line component (11). The present invention is also directed to a surgical separator assembly (60) for use in separating at least two surgical component during a surgical procedure in a vessel.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/03871

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 17/04
US CL : 606/148

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/148, 147,144,139, 224, 232

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,447,512 A (WILSON et al.) 05 September 1995, figs. 1, 5, 8 and 10.	1-19
X	US 5,314,463 A (CAMPS et al.) 24 May 1994, figs. 1 and 18.	1-19
X	US 4,702,250 A (OVIL et al.) 27 October 1987, figs. 12 and 13.	20-22
X, P	US 5,871,489 A (OVIL) 16 February 1999, fig. 1.	20-22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 12 MAY 2000	Date of mailing of the international search report 13 JUN 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer LIEN NGO Telephone No. (703) 305-0294

Form PCT/ISA/210 (second sheet) (July 1998) *

NOTES TO FORM PCT/ISA/220

These Notes are intended to give the basic instructions concerning the filing of amendments under Article 19. The Notes are based on the requirements of the Patent Cooperation Treaty and of the Regulations and the Administrative Instructions under that Treaty. In case of discrepancy between these Notes and those requirements, the latter are applicable. F r more detailed information, see also the PCT Applicant's Guide, a publication of WIPO.

In these Notes, "Article", "Rule" and "Section" refer to the provisions of the PCT, the PCT Regulations and the PCT Administrative Instructions, respectively.

INSTRUCTIONS CONCERNING AMENDMENTS UNDER ARTICLE 19

The applicant has, after having received the international search report, one opportunity to amend the claims of the international application. It should however be emphasized that, since all parts of the international application (claims, description and drawings) may be amended during the international preliminary examination procedure, there is usually no need to file amendments of the claims under Article 19 except where, e.g. the applicant wants the latter to be published for the purposes of provisional protection or has another reason for amending the claims before international publication. Furthermore, it should be emphasized that provisional protection is available in some States only.

What parts of the international application may be amended ?

The claims only.

The description and the drawings may only be amended during international preliminary examination under Chapter II.

When ? **Within 2 months from the date of transmittal of the international search report or 16 months from the priority date, whichever time limit expires later. It should be noted, however, that the amendments will be considered as having been received on time if they are received by the International Bureau after the expiration of the applicable time limit but before the completion of the technical preparations for international publication (Rule 46.1).**

Where not to file the amendments ?

The amendments may only be filed with the International Bureau and not with the receiving Office or the International Searching Authority (Rule 46.2).

Where a demand for international preliminary examination has been/is filed, see below.

How ? Either by cancelling one or more entire claims, by adding one or more new claims or by amending the text of one or more of the claims as filed.

A replacement sheet must be submitted for each sheet of the claims which, on account of an amendment or amendments, differs from the sheet originally filed.

All the claims appearing on a replacement sheet must be numbered in Arabic numerals. Where a claim is cancelled, no renumbering of the other claims is required. In all cases where claims are renumbered, they must be renumbered consecutively (Administrative Instructions, Section 205(b)).

What documents must/may accompany the amendments ?

Letter **(Section 205(b)):**

The amendments must be submitted with a letter.

The letter will not be published with the international application and the amended claims. It should not be confounded with the "Statement under Article 19(1)" (see below, under "Statement under Article 19(1)").

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

(i) the claim is unchanged;
(ii) the claim is cancelled;
(iii) the claim is new;
(iv) the claim replaces one or more claims as filed;
(v) the claim is the result of the division of a claim as filed.

FOR THE PURPOSES OF INFORMATION ONLY

Codes used to identify States party to the PCT on the front pages of pamphlets publishing international applications under the PCT.

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SURGICAL GUIDE LINE ASSEMBLY AND SEPARATOR ASSEMBLY FOR USE DURING A SURGICAL PROCEDURE

CROSS REFERENCE TO RELATED APPLICATION

This application relates to and claims priority on U.S. Provisional Application No. 60/118,779, filed February 5, 1999, and 60/137,702, filed June 7, 1999.

FIELD OF THE INVENTION

The present invention relates generally to a surgical guide line assembly. In particular, the present invention is directed to a surgical guide line assembly for use in remote controlled surgical procedures. The present invention also related to a separator assembly for use in connection with the surgical guide line assembly to ensure that surgical components do not become entwined during a surgical procedure.

BACKGROUND OF THE INVENTION

Recent developments in the repair of abdominal aortic aneurysms permit minimally invasive surgical procedures through either an axillary or brachial incision or both. This requires the remote manipulation of both a repair graft and surgical components.

OBJECTS OF THE INVENTION

It is an object of the present invention to provide a guide line assembly for use in intravascular surgical procedures.

It is another object of the present invention to provide a guide line assembly for use in the manipulation of a surgical component within a vessel during an intravascular surgical procedure.

It is another object of the present invention to provide a guide line assembly for use in the manipulation of a repair graft assembly within a vessel during a surgical procedure for repairing an aneurysm.

It is another object of the present invention to provide a guide line assembly having a simple construction.

It is another object of the present invention to provide a guide line assembly that can be releasably secured to a surgical component for manipulation of the component within a vessel during a surgical procedure.

It is another object of the present invention to provide a guide line assembly that is capable of being attached to a surgical component at least one location.

It is another object of the present invention to provide a guide line assembly having a flexible curved end portion.

It is another object of the present invention to provide a separator assembly for use during a surgical procedure to ensure that surgical components do not become entwined during a surgical procedure.

It is another object of the present invention to provide a separator assembly that is capable of manipulating a graft assembly within a vessel.

It is another object of the present invention to provide a separator assembly having a separating assembly that is capable of rotating within the vessel.

It is another object of the present invention to provide a separator assembly having a separating assembly that is capable of being selectively locked with the vessel.

SUMMARY OF THE INVENTION

The present invention is directed to a surgical guide line assembly for use during a surgical procedure. The surgical guide line assembly permits the manipulation of a surgical component within a vessel during a surgical procedure, such as for example an intravascular procedure. The surgical guide line assembly includes a guide line component having a proximal end and a distal end, and at least one suture secured to the distal end of the guide line component. The surgical guide line assembly may further include a surgical needle connected to each of the at least one suture. The surgical guide line according to the present invention may further include a broad line assembly that is positioned around the distal end of the guide line component and a portion of the at least one suture. The broad line assembly produces a flexible curved end portion of the guide line assembly.

The surgical guide line assembly may further include a control assembly connected to the guide line component. The control assembly permits manipulation of the guide line assembly within the vessel from a remote location.

The present invention is also directed to a surgical guide line assembly for use during a surgical procedure. The surgical guide assembly permits the manipulation of a surgical component within a vessel during a surgical procedure, such as for example an intravascular procedure. The surgical guide line assembly includes a guide line component having a

proximal end and a distal end, and at least one suture secured to the distal end of the guide line component. The surgical guide line assembly may further include a surgical needle connected to each of the at least one suture. The at least one suture according to the present invention may be secured to the guide line component in one of several ways. It may be bonded directly to the component. The at least one suture may be secured to the guide line component within a formed cavity in the distal end of the guide line component. Alternatively, the suture may be secured to the distal end of the guide line component within a central passageway in the component.

In accordance with embodiments of the present invention, the guide line component may have a bent portion located adjacent the distal end. Alternatively, the guide line component may have an articulated portion located adjacent the distal end. The control assembly is capable of permitting manipulation of the articulated portion of the guide line component.

The present invention is also directed to a surgical separator assembly for use in separating at least two surgical components during a surgical procedure in a vessel. The surgical separator assembly includes a separating assembly for receiving the at least two surgical components during the surgical procedure. The surgical separator assembly further includes an advancing assembly for advancing the separating assembly within the vessel during the surgical procedure. The advancing assembly may include a catheter. The separating assembly may be rotatably connected to the advancing assembly. The separator assembly further includes a control assembly for selectively locking the separating assembly to prevent rotation of the separating assembly. In accordance with the present invention, the separating assembly may include at least two apertures therein. Each of the apertures is sized to receive at least a portion of a surgical component therein.

The present invention is also directed to a surgical system for use during a surgical procedure within a vessel. The surgical system includes both the guide line assemblies described herein in combination with the surgical separator assembly.

It is to be understood that both the foregoing general description and the following detailed description are exemplary and explanatory only, and are not restrictive of the invention, as claimed. The accompanying drawings, which are incorporated herein by reference, and which constitute a part of this specification, illustrate certain embodiments of

the invention, and together with the detailed description serve to explain the principles of the present invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The invention will be described in conjunction with the following drawing in which like reference numerals designate like elements and wherein:

Fig. 1 is a perspective view of a guide line assembly according to an embodiment of the present invention;

Fig. 2 is a schematic view of the guide line assembly according to Fig. 1 secured to a repair graft;

Fig. 3 is a schematic view of a guide line assembly according to another embodiment of the present invention secured to a repair graft;

Fig. 4 is a cross section of the guide line component of Figs. 1-3 according to one embodiment of the present invention;

Fig. 5 is a cross section of the guide line component of Figs. 1-3 according to another embodiment of the present invention;

Fig. 6 is a cross section of the guide line component of Figs. 1-3 according to another embodiment of the present invention;

Fig. 7 is a cross section of the guide line component of Figs, 1-3 according to another embodiment of the present invention;

Fig. 8 is a partial cross section of a guide line assembly according to another embodiment of the present invention;

Fig. 9 is a perspective view of the guide line assembly according to the embodiment of Fig. 8;

Fig. 10 is a perspective view of a guide line assembly according to another embodiment of the present invention;

Fig. 11 is a perspective view of the end portion of the guide line component according to an embodiment of the present invention;

Fig. 12 is a perspective view of the end portion of the guide line component according to another embodiment of the present invention;

Fig. 13 is a perspective view of the end portion of the guide line component according to another embodiment of the present invention;

Fig. 14 is a perspective view of a guide line assembly according to another embodiment of the present invention;

Fig. 15 is a perspective view of a guide line assembly according to another embodiment of the present invention;

Fig. 16 is a perspective view of a guide line and suture separating assembly according tot he present invention;

Fig. 17 is a cross section view of the head of the separating assembly of Fig. 16; and

Fig. 18 is a schematic view of the separator assembly of Fig. 16 in accordance with the present invention used to position a graft assembly within a vessel.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

The above-described figures depict various surgical guide line assemblies according to embodiments of the present invention. These guide line assemblies are adapted for use in connection with the surgical repair of an aneurysms, as described in copending U.S. Patent Application No. 09/121,706, entitled "SURGICAL CUTTING DEVICE" filed on July 24, 1998, the disclosure of which is incorporated herein by reference. At least one guide line assembly may be used to align and manoeuvre a repair graft, disclosed in U.S. Patent Application Nos. 08/896,415, entitled "METHOD AND APPARATUS FOR THE SURGICAL REPAIR OF ANEURYSMS" filed on July 18, 1997, now U.S. Patent No. 5,944,750, specification of which is incorporated herein by reference, within an infra, juxta or renal positioning. The guide line assemblies may be radially positioned about the perimeter of the proximal lip of the repair graft assembly and extend caudad to the femoral incision and thereafter to a hand controller **2**, shown in Fig. 2. It is also contemplated that the guide line assemblies may extend cephalad to the axillary or brachial incision. The operation of the hand controller permits the manipulation of the at least one guide line assembly, which in turn adjusts the positioning of the repair graft assembly within the vessel during the surgical procedure.

Use of the various guide line assemblies disclosed herein according to the present invention is not limited to the repair of aneurysms. It is contemplated by the present inventors that the guide line assemblies disclosed herein according to the present invention may be used in connection with numerous intravascular procedures.

The guide line assembly **10** according to an embodiment of the present invention, depicted in Fig. 1, will now be described in greater detail. Guide line assembly **10** includes a guideline component **11**. The guide line component **11** has a distal end which is located within the vessel during the surgical procedure and a proximal end which extends from within the vessel. The guide line assembly **10** further includes at least one suture **12** connected to the guide line component **11**. The at least one suture **12** is secured to one end of the guide line component **11**. The guide line component **11** has sufficient length such that it may extend from within the vessel caudad to the femoral incision and thereafter to a hand controller **2**. The guide line component **11** is preferably formed from nitonol. It, however, is contemplated that the guide line component **11** may be formed from a similar biocompatible material.

At least one suture **12** is secured to the guide line component **11**. The embodiment of the present invention illustrated in Figs. 1 and 2 includes a pair of sutures **12**. The present invention, however, is not limited to a pair of sutures **12**. It is contemplated that a single suture **12** may be used as shown in Fig. 3. Furthermore, it is also contemplated that a plurality of sutures may extend from the distal end of the guide line component **11**. The sutures **12** are mechanically coupled to the distal end of the guide line component **11**. For example, the at least one suture **12** may be bonded to the end of the guide line component **11**, as shown for example in Fig. 1.

Other forms of coupling are considered to be well within the scope of the present invention. For example, another coupling attachment is illustrated in the embodiment depicted in Fig. 8. In this embodiment, the at least one suture **12** is crimped to the end of the guide line component **11**. A formed cavity **14** is provided in the end portion of the guide line component **11**. The at least one suture **12** is inserted into the formed cavity **14** such that the at least one suture **12** is held firmly in place upon crimping of the end of the guide line component **11**. Additionally, an insert **15** may be provided within the cavity **14**. The at least one suture **12** may be positioned around the insert **15** such that upon crimping of the end of the guide line component **11** the at least suture **12** is firmly secured to it. Fig. 9 is a perspective view of the end of the guide line component **11** in the crimped position.

Fig. 10 illustrates another embodiment of the coupling attachment for the guide line component **11**. In this embodiment, the at least one suture **12** is crimped within the hollow

portion, shown in Figs. 4-7, of the guide line component **11**. With this arrangement, no secondary drilling is required. In the embodiments illustrated in Figs. 8-10, detailing of the transition between the guide line component **11** and the at least one suture **12** may be required to remove potential burrs as well as round the corners to prevent the unintentional separation of the guide line component **11** and the at least one suture **12**. Furthermore, this detailing will prevent the guide line assembly **10** from becoming unintentionally caught within the vessel.

The guideline assembly **10** according to embodiments of the present invention includes a surgical needle assembly **13** secured to one end of the suture **12**. The provision of the surgical needle assembly **13** facilitates the attachment of the guide line assembly **10** to a repair graft assembly **1**, as shown for example in Figs. 2 and 3.

The guide line component **11** may be formed in one of several profiles, as depicted in Figs. 4-7. Fig. 4 illustrates a guide line component **11** according to the present invention having a rectangular profile **111** having rounded corners. The rounded corners facilitate smooth movement of the guide line assembly **10** within the vessel. The rectangular profile **111** may have a solid construction. A hollow or tubular construction having a central aperture **1110**, shown in phantom, is also considered to be well within the scope of the present invention.

Fig. 5 illustrates a profile for the guide line component **11** according to another embodiment of the present invention. The guide line component **11** illustrated in Fig. 5 has an elongated or obround profile **112** having rounded ends. As discussed above in connection with the rounded corners, the rounded ends facilitate smooth movement of the guide line assembly **10** within the vessel. Additionally, the elongated profile **112** may have a solid construction. A hollow or tubular construction having a central aperture **1120**, shown in phantom, is also considered to be well within the scope of the present invention.

Fig. 6 illustrates a profile for the guide line component **11** according to another embodiment of the present invention. The guide line component **11** illustrated in Fig. 6 has an elliptical profile **113**. The elongated profile **113** may have a solid construction. A hollow or tubular construction having a central aperture **1130**, shown in phantom, is also considered to be well within the scope of the present invention.

Fig. 7 illustrates a profile for the guide line component **11** according to yet another embodiment of the present invention. The guide line component **11** illustrated in Fig. 7 has a circular profile **114**. The circular profile **114** may have a solid construction. A hollow or tubular construction having a central aperture **1140**, shown in phantom, is also considered to be well within the scope of the present invention.

In accordance with embodiments of the present invention, the distal end of the guide line component **11** may have a linear orientation, as shown in Fig. 11. Alternatively, the distal end of the guide line component **11** may have a bent configuration **41**, as shown in Fig. **12**. The distal end of the guide line component **11** may be articulated to facilitate manipulation of the guide line assembly **10** within the vessel for positioning a surgical component such as for example a repair graft assembly **2**, as shown in Fig. 13. In this embodiment, the guide line component **11** includes an articulated segment **31** located adjacent the distal end. The articulated segment **31** may be manually adjusted by the surgeon. It, however, is contemplated that the articulated segment **31** may be remotely adjusted using the hand controller **2** or other suitable manipulation assembly.

The operation of the guide line assembly **10** will now be described in connection with a repair graft assembly **2**. It, however, is contemplated by the inventors of the present invention that the guide line assembly **10** may be used with other surgical components for use in other intravascular procedures. The guide line assembly **10** is secured to the repair graft assembly **2**. Specifically, the surgical needle **13** is inserted through the lip of the repair graft assembly **2**. The surgical needle **13** is then looped around the suture **12** to secure the guide line assembly **10** to the repair graft assembly **2**. The surgical needle **13** is then removed. The repair graft **2** can then be inserted and maneuvered within the vessel. The positioning of the repair graft **2** within the vessel can be adjusted using the hand controller **2**.

The guide line assembly **20** according to another embodiment of the present invention, depicted in Fig. 14, will now be described in greater detail. Guide line assembly **20** includes a guide line component **21**. The guide line component **21** is fairly stiff. The guide line component **21** has a distal end which is located within the vessel during the surgical procedure and a proximal end which extends from within the vessel. The guide line assembly **20** is manipulated within the vessel adjacent the proximal end of the guide line

component **21**. The guide line assembly **20** further includes at least one suture **22** connected to the guide line component **21**. The at least one suture **22** is secured to one end of the guide line component **21**. The guide line component **21** has sufficient length such that it may extend from within the vessel caudad to the femoral incision and thereafter to a hand controller as shown in Fig. 1 in connection with guide line assembly **10**. The guide line component **21** is preferably formed from nitonol. It, however, is contemplated that the guide line component **11** may be formed from a similar biocompatible material.

At least one suture **22** is secured to the guide line component **21**. The embodiment of the present invention illustrated in Fig. 14 includes a pair of sutures **22**. The present invention, however, is not limited to a single suture **22**. It is contemplated that more than one suture **22** may be used. The suture **22** is mechanically coupled to the distal end of the guide line component **21**. For example, the at least one suture **22** may be bonded and/or crimped to the end of the guide line component **21**. Other forms of coupling, however, are considered to be well within the scope of the present invention.

The guide line assembly **20** according to embodiments of the present invention includes a surgical needle assembly **23** secured to one end of the suture **22**. The provision of the surgical needle assembly **23** facilitates the attachment of the guide line assembly **10** to a repair graft assembly **20** or other suitable surgical component within the vessel.

The distal end of the guide line assembly **20** may be curved, as shown in Fig. 14. A broad line assembly **24** surrounds the suture **22** adjacent the distal end of the guide line component **21**. The broad line assembly **24** permits the distal end of the guide line assembly **20** to retain its curved shape. The broad line assembly **24** is preferably flexible. It is preferably formed from a spring type material. The end of the guide line component **21** and the suture **22** may be coated and/or sheathed with a thin layer **25** of Gore-Tex® or other suitable material. The thin layer **25** prevents the curved end portion of the guide line assembly **20** from snagging when it is manipulated within the vessel and/or removed from the vessel.

A guide line assembly **50** according to another embodiment of the present invention is illustrated in Fig. 15. The guide line assembly **50** includes a guide line component **51**, which is fairly stiff. The component **51** may be formed from a thin metal rod or needle. The component **51** has a distal end that is located within the vessel during the surgical procedure

and a proximal end that extends from within the vessel. The guide line assembly **50** further includes at least one suture **52** secured to the distal end of the component **51**. A surgical needle assembly **53** is secured to one end of the suture **52**. The surgical needle assembly **53** may be straight or curved, as shown in Fig. 15.

During a surgical procedure, it is possible that several guide line assemblies, described above, may be located within the vessel. It is possible that during the surgical procedure these guide line assemblies and sutures may become entwined, which may hamper the surgical procedure. Therefore, it is desirable to provide an assembly that is capable of separating any entwined guide line assemblies and sutures. A suture and guide line separator assembly **60** will now be described in connection with Figs. 16 and 17. The separator assembly **60** includes a catheter assembly **61**. One end of the catheter assembly **61** includes a separating assembly **62** connected thereto. The separating assembly **62** is capable of rotating about the axis of the catheter assembly **61**. The separating assembly **62** includes a plurality of opening **621** are sized to receive a guide line assembly or a suture therein. An opposite end of the catheter assembly **61** includes a handle assembly **63**. The handle assembly **63**, when compressed, locks the separating assembly **62** in place such that it cannot rotate about the axis of the catheter assembly **61**.

The operation of the separator assembly **60** will now be described. The free ends of the suture and guide line assemblies are threaded through the openings **621** in the separating assembly **62**. The separator assembly **60** is advanced within the vessel along the sutures and guide line assemblies. The free ends of the sutures and the guide line assemblies located outside the vessel are preferably held in place to prevent insertion into the vessel while the separator assembly **60** is advanced to its furthest most position within the vessel. While the separator assembly **60** is advanced, the separating assembly **62** freely rotates about the catheter assembly **61**. Once the separator assembly **60** reaches its furthest position within the vessel, the handle assembly **63** is operated to lock the separating assembly **62** to prevent its rotation. The separator assembly **60** may then be withdrawn from the vessel during which time the sutures and guide line assemblies may be straightened out and untangled. It is contemplated that the separator assembly **60** may be used in connection with any of the above described guide line assemblies. It is further contemplated that the separator assembly **60** may be used to separate sutures or a combination of sutures and guide line assemblies. It is

further contemplated that the separator assembly **60** may be used in connection with any other surgical component that is capable of being entangled within a vessel during a surgical procedure.

It is further contemplated that the separator assembly **60** may be used to position and rotate a graft assembly **7** within the vessel, as shown in Fig. 18. A single suture **5** may be fed through two openings **621** in the separating assembly **62** and loops **71** on the graft assembly **7**. The graft assembly **7** may be advanced into position within the vessel by inserting the separator assembly **60** into the vessel. As the separator assembly **60** is inserted, the graft assembly **7** and the separating assembly **62** will rotate freely about the axis of the catheter assembly **61**. When the graft assembly **7** reaches the desired location, the handle assembly **63** is operated to prevent rotation of separating assembly **62**. The catheter assembly **61** may then be rotated to position the graft assembly **7** in the desired location.

It will be apparent to those skilled in the arts that various modifications and variations can be made in the construction and configuration of the present invention, without departing from the scope or spirit of the invention. It is intended that the present invention cover the modifications and variations of the invention, provided they come within the scope of the appended claims and their equivalence.

WHAT IS CLAIMED IS:

1. A surgical guide line assembly for use during a surgical procedure, said surgical guide line assembly comprising:

a guide line component having a proximal end and a distal end; and

at least one suture secured to the distal end of said guide line component.

2. The surgical guide line assembly according to Claim 1, further comprising:

a control assembly connected to said guide line component, wherein said control assembly permits manipulation of said guide line assembly.

3. The surgical guide line assembly according to Claim 1, wherein each of said at least one suture includes a first end secured to said distal end of said guide line component, and a second free end, said surgical guide line assembly further comprising:

a surgical needle connected to said second end of said at least one suture.

4. The surgical guide line assembly according to Claim 1, wherein said guide line component has a bent portion located adjacent said distal end.

5. The surgical guide line assembly according to Claim 1, wherein said guide line component has an articulated portion located adjacent said distal end.

6. The surgical guide line assembly according to Claim 5, further comprising:

a control assembly connected to said guide line component, wherein said control assembly enables manipulation of said guide line assembly.

7. The surgical guide line assembly according to Claim 6, wherein said control assembly enables manipulation of said articulated portion of said guide line component.

8. The surgical guide line assembly according to Claim 1, wherein said at least one suture is secured to said guide line component within a formed cavity in said distal end of said guide line component.

9. The surgical guide line assembly according to Claim 1, wherein said guide line component has a central passageway extending therein, said at least one suture is secured to said distal end of said guide line component within said central passageway.

10. The surgical guide line assembly according to Claim 1, wherein said at least one suture is bonded to said distal end of said guide line component.

11. A surgical guide line assembly for use in a vessel during a surgical procedure, said surgical guide line assembly comprising:

a guide line component having a proximal end and a distal end;

at least one suture secured to the distal end of said guide line component;

a control assembly connected to said guide line component adjacent said proximal end, wherein said control assembly enables manipulation of said guide line assembly within the vessel; and

a surgical needle connected to said at least one suture.

12. The surgical guide line assembly according to Claim 11, wherein said guide line component has a bent portion located adjacent said distal end.

13. The surgical guide line assembly according to Claim 11, wherein said guide line component has an articulated portion located adjacent said distal end.

14. The surgical guide line assembly according to Claim 13, wherein said control assembly permits manipulation of said articulated portion of said guide line component.

15. A surgical guide line assembly for use during a surgical procedure, said surgical guide line assembly comprising:

a guide line component having a proximal end and a distal end;

at least one suture secured to the distal end of said guide line component; and

a broad line assembly positioned around said distal end of said guide line component and a portion of said at least one suture.

16. The surgical guide line assembly according to Claim 15, wherein said broad line assembly produces a flexible curved end portion of said guide line assembly.

17. The surgical guide line assembly according to Claim 15, wherein each of said at least one suture includes a first end secured to said distal end of said guide line component, and a second free end, said surgical guide line assembly further comprising:

a surgical needle connected to said second end of said at least one suture.

18. The surgical guide line assembly according to Claim 15, further comprising:

a thin layer of material positioned about said distal end of said guide line component and said at least one suture adjacent said broad line assembly.

19. The surgical guide line assembly according to Claim 18, wherein said thin layer of material is formed from Gore-Tex®.

20. A surgical separator assembly for use in separating at least two surgical components during a surgical procedure in a vessel, said surgical separator assembly comprising:

separating means for receiving the at least two surgical components during the surgical procedure;

advancing means for advancing said separating means within the vessel during the surgical procedure, wherein said separating means is rotatably connected to said advancing means; and

control means for selectively locking said separating means to prevent rotation of said separating means about said advancing means.

21. The surgical separator assembly according to Claim 20, wherein said separating means includes at least two apertures therein, wherein each of said at least two apertures is sized to receive at least a portion of the surgical component therein.

22. A surgical system for use during a surgical procedure within a vessel, said surgical system comprising:

at least two surgical guide line assemblies for use during the surgical procedure, wherein each of said surgical guide line assemblies comprising a guide line component having a proximal end and a distal end, and at least one suture secured to the distal end of said guide line component; and

a surgical separator assembly for use in separating said at least two surgical guide line assemblies during the surgical procedure, wherein said surgical separator assembly comprising separating means for receiving the at least two surgical components during the surgical procedure, advancing means for advancing said separating means within the vessel during the surgical procedure, wherein said separating means is rotatably connected to said advancing means, and control means for selectively locking said separating means to prevent rotation of said separating means about said advancing means.

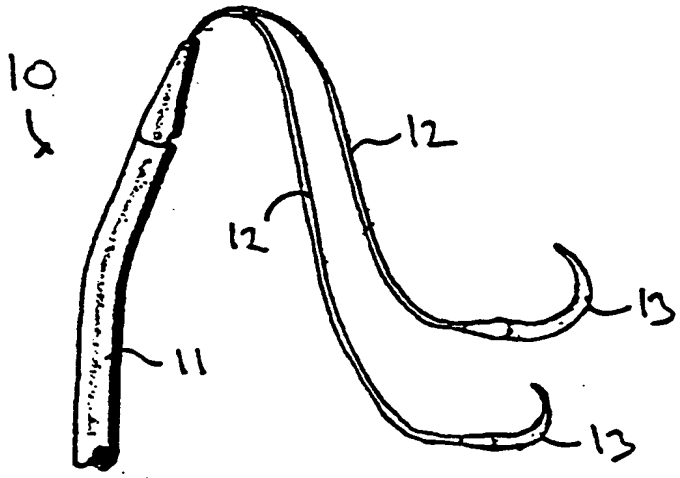
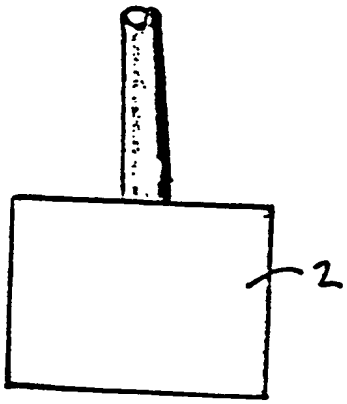


FIG. 1



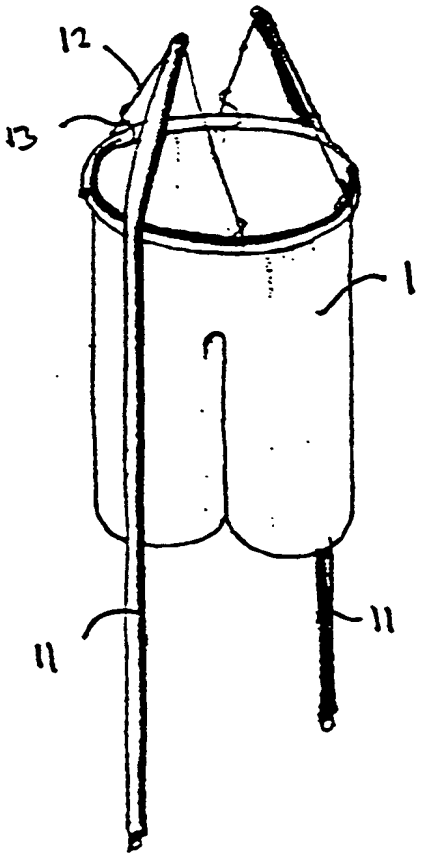


FIG. 2

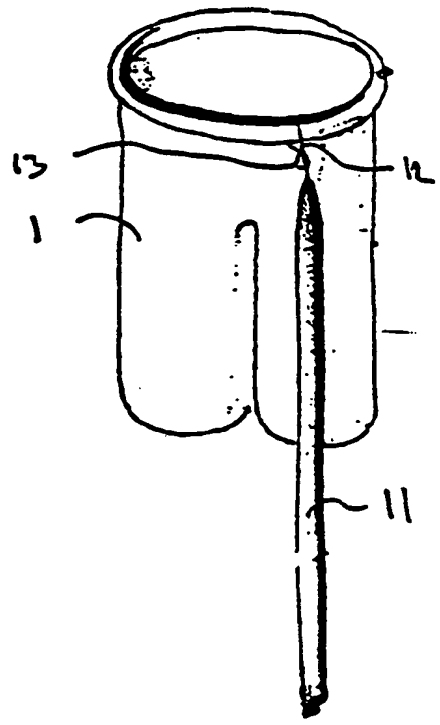


FIG. 3

FIG. 4

FIG. 5

FIG. 6

FIG. 7

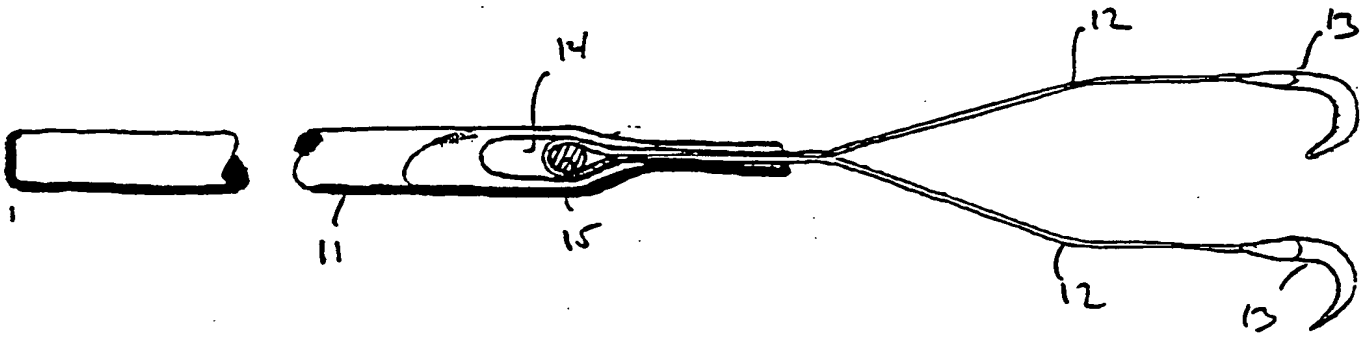


FIG. 8

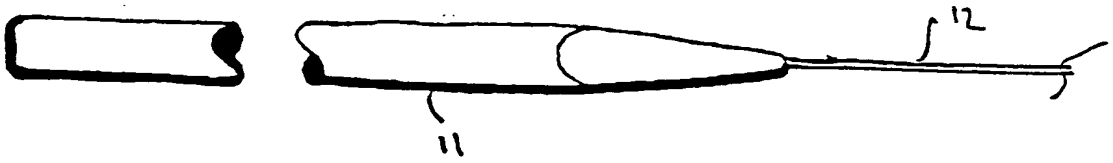


FIG. 9

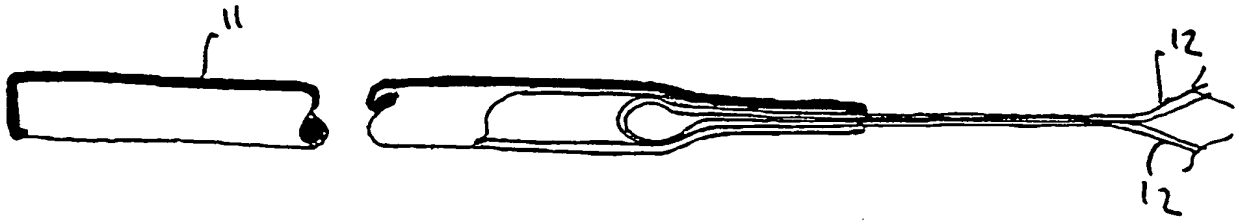


FIG. 10

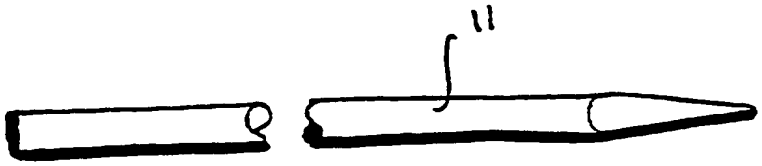


FIG. 11

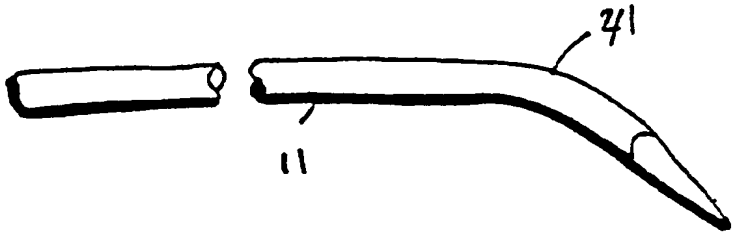


FIG. 12

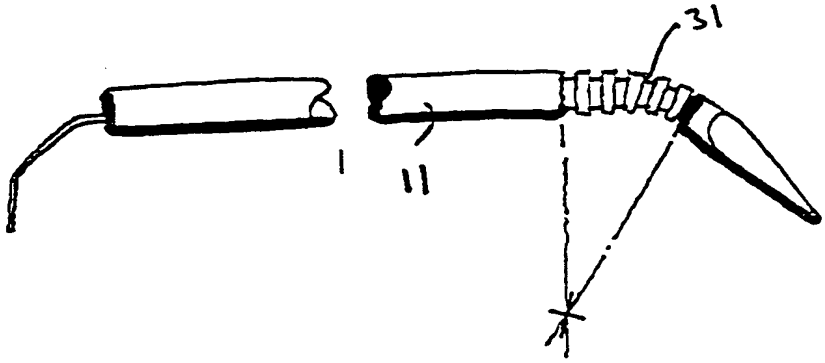


FIG. 13

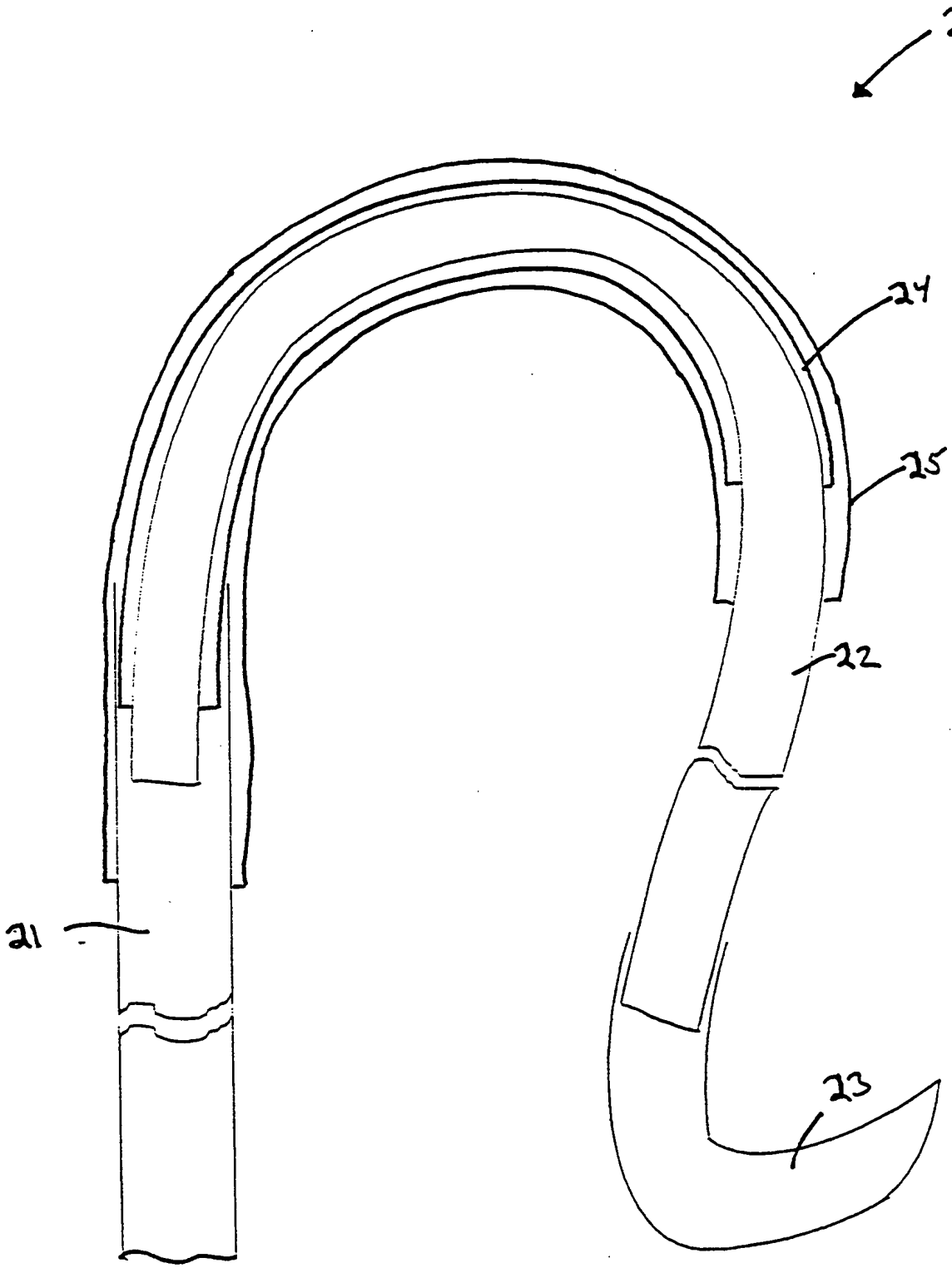


FIG.14

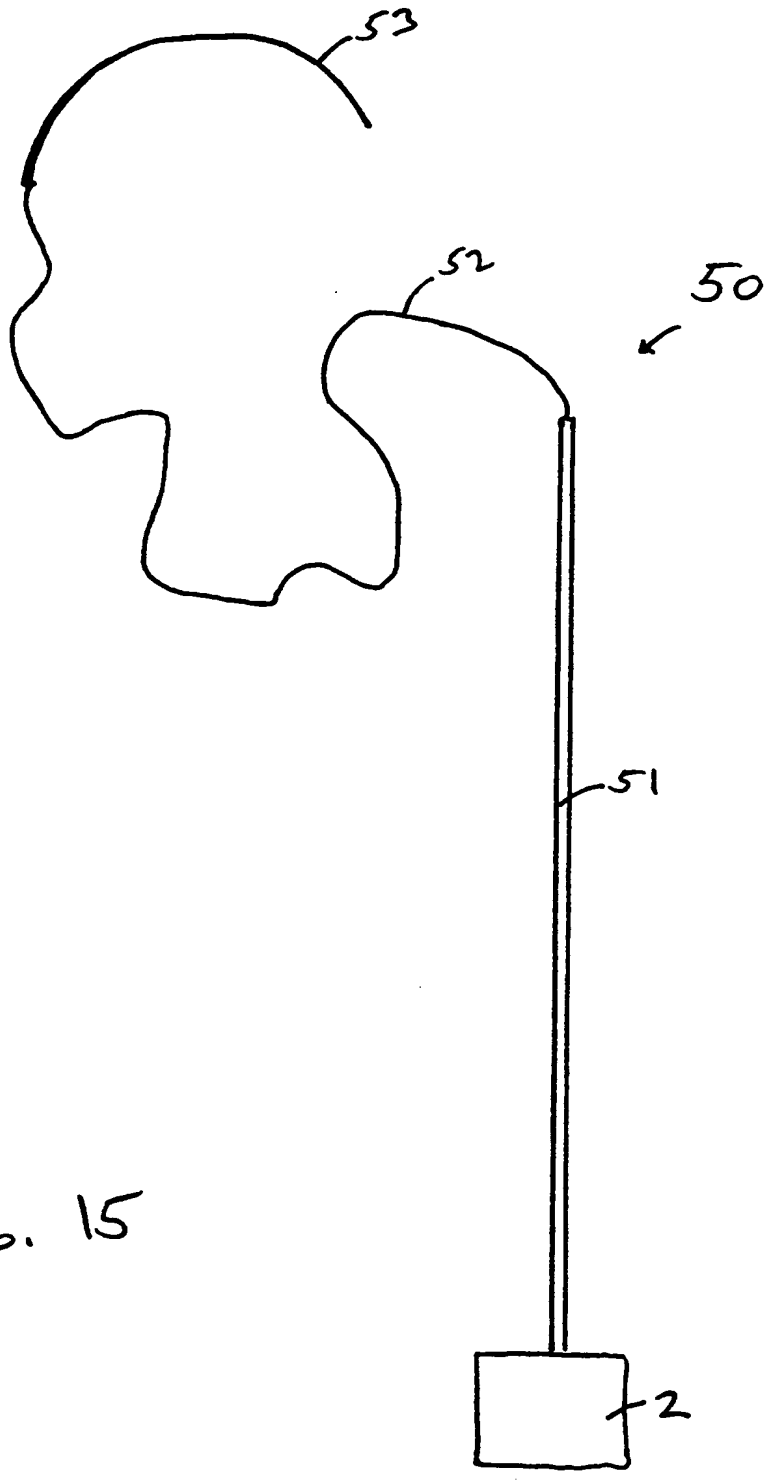


FIG. 15

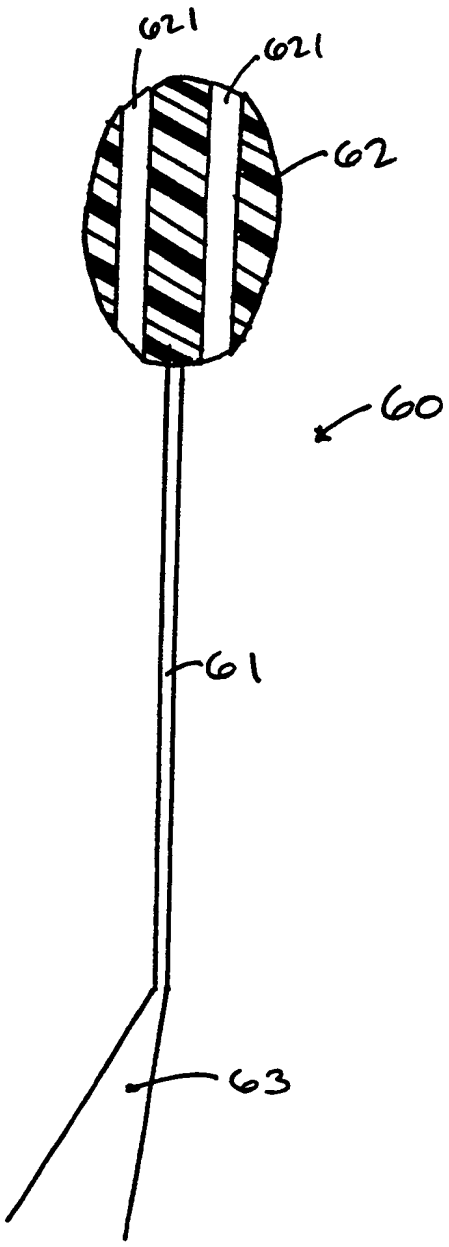


FIG. 16

FIG. 17

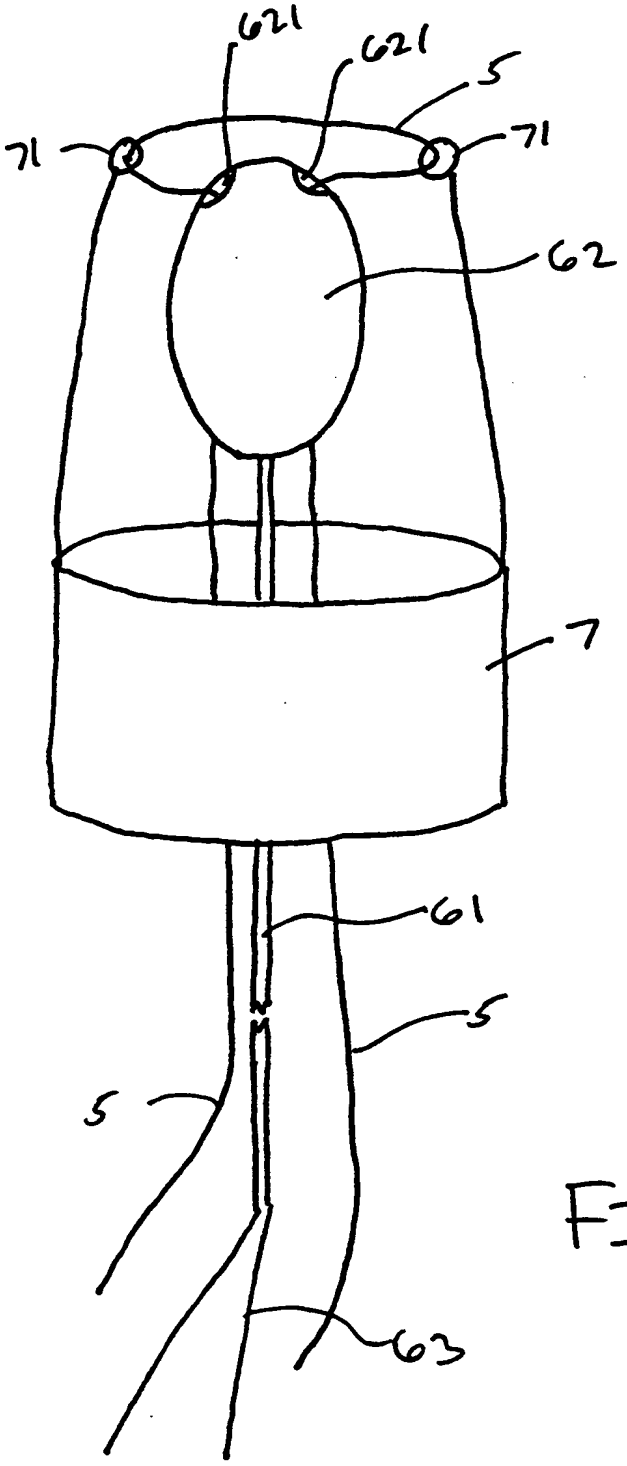


FIG. 18

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US00/03871

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61B 17/04
US CL : 606/148

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/148, 147,144,139, 224, 232

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

EAST

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5,447,512 A (WILSON et al.) 05 September 1995, figs. 1, 5, 8 and 10.	1-19
X	US 5,314,463 A (CAMPS et al.) 24 May 1994, figs. 1 and 18.	1-19
X	US 4,702,250 A (OVIL et al.) 27 October 1987, figs. 12 and 13.	20-22
X, P	US 5,871,489 A (OVIL) 16 February 1999, fig. 1.	20-22

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"A"	document defining the general state of the art which is not considered to be of particular relevance	"X"	document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"E"	earlier document published on or after the international filing date	"Y"	document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"L"	document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"&"	document member of the same patent family
"O"	document referring to an oral disclosure, use, exhibition or other means		
"P"	document published prior to the international filing date but later than the priority date claimed		

Date of the actual completion of the international search 12 MAY 2000	Date of mailing of the international search report 13 JUN 2000
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer LIEN NGO Telephone No. (703) 305-0294

Form PCT/ISA/210 (second sheet) (July 1998) ★